

AMENDED IN SENATE JUNE 9, 2004
AMENDED IN ASSEMBLY MAY 20, 2004
AMENDED IN ASSEMBLY APRIL 22, 2004
AMENDED IN ASSEMBLY APRIL 15, 2004
AMENDED IN ASSEMBLY APRIL 12, 2004

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL

No. 1960

**Introduced by Assembly Members Pavley, Chu, Frommer, and
Ridley-Thomas**
**(~~Coauthor: Assembly Member Koretz~~ Coauthors: Assembly
Members Chan and Koretz)**
(Coauthor: Senator Kuehl)

February 12, 2004

An act to add Article 8 (commencing with Section 4130) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacy benefits management.

LEGISLATIVE COUNSEL'S DIGEST

AB 1960, as amended, Pavley. Pharmacy benefits management.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy and makes it responsible for the regulation and licensure of persons engaged in pharmacy practices relating to the furnishing of dangerous drugs, as defined. Under existing law, a violation of the Pharmacy Law is a crime.

This bill would define the term “pharmacy benefits management” as the administration or management of prescription drug benefits. The bill would also define the term “pharmacy benefits manager” as an entity that performs pharmacy benefits management. The bill would require a pharmacy benefits manager to make specified disclosures to its purchasers and prospective purchasers, including specified information about the pharmacy benefit manager’s revenues and its drug formularies, and to make specified disclosures to the public upon request. The bill would also establish certain standards and requirements with regard to pharmacy benefits management contracts and the provision of certain drugs. The bill would impose certain requirements on the membership of a pharmacy and therapeutics committee for a pharmacy benefits manager. The bill would also require a pharmacy benefits manager to meet certain conditions before substituting a prescribed medication.

Because the bill would create additional requirements under the Pharmacy Law, a violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Article 8 (commencing with Section 4130) is
2 added to Chapter 9 of Division 2 of the Business and Professions
3 Code, to read:

4

5 Article 8. Pharmacy Benefits Management

6

7 4130. For purposes of this article, the following definitions
8 shall apply:

9 (a) “Labeler” means any person who receives prescription
10 drugs from a manufacturer or wholesaler and repackages those
11 drugs for later retail sale and who has a labeler code from the



1 federal Food and Drug Administration under Section 207.20 of
2 Title 21 of the Code of Federal Regulations.

3 (b) “Pharmacy benefits management” is the administration or
4 management of prescription drug benefits. Pharmacy benefits
5 management includes the procurement of prescription drugs at a
6 negotiated rate for dispensation within this state, the processing of
7 prescription drug claims, and the administration of payments
8 related to prescription drug claims.

9 (c) “Pharmacy benefits manager” is any person who performs
10 pharmacy benefits management. The term does not include a
11 health care service plan or health insurer if the health care service
12 plan or health insurer offers or provides pharmacy benefits
13 management services and if those services are offered or provided
14 only to enrollees, subscribers, or insureds who are also covered by
15 health benefits offered or provided by that health care service plan
16 or health insurer, nor does the term include an affiliate, subsidiary,
17 or other related entity of the health care service plan or health
18 insurer that would otherwise qualify as a pharmacy benefits
19 manager, as long as the services offered or provided by the related
20 entity are offered or provided only to enrollees, subscribers, or
21 insureds who are also covered by the health benefits offered or
22 provided by that health care service plan or health insurer.

23 (d) “Prospective purchaser” is any person to whom a
24 pharmacy benefits manager offers to provide pharmacy benefit
25 management services.

26 (e) “Purchaser” is any person who enters into an agreement
27 with a pharmacy benefits manager for the provision of pharmacy
28 benefit management services.

29 4131. A pharmacy benefits manager shall disclose to the
30 purchaser in writing all of the following:

31 (a) The aggregate amount, ~~and for a specified list of therapeutic~~
32 ~~classes, the specific amount,~~ of all rebates and other retrospective
33 utilization discounts that the pharmacy benefits manager receives,
34 directly or indirectly, from pharmaceutical manufacturers or
35 labelers in connection with prescription drug benefits ~~related~~
36 ~~specific to the purchaser. A therapeutic class shall include at least~~
37 ~~two drugs.~~

38 (b) *For a specified list of therapeutic classes, the aggregate*
39 *amount for each therapeutic class of all rebates and other*
40 *retrospective utilization discounts that the pharmacy benefits*

1 *manager receives, directly or indirectly, from pharmaceutical*
2 *manufacturers or labelers in connection with prescription drug*
3 *benefits specific to the purchaser. A therapeutic class shall include*
4 *at least two drugs.*

5 (c) The nature, type, and amount of all other revenue that the
6 pharmacy benefits manager receives, directly or indirectly, from
7 pharmaceutical manufacturers or labelers in connection with
8 prescription drug benefits related to the purchaser.

9 ~~(c)~~

10 (d) Any prescription drug utilization information related to
11 utilization by the purchaser's enrollees or aggregate utilization
12 data that is not specific to an individual consumer, prescriber, or
13 purchaser.

14 ~~(d)~~

15 (e) Any administrative or other fees charged by the pharmacy
16 benefits manager to the purchaser.

17 ~~(e) The credentials of members of any pharmacy and~~
18 ~~therapeutic committee and any direct or indirect financial~~
19 ~~relationships between committee members and the~~
20 ~~pharmaceutical industry.~~

21 (f) Any arrangements with prescribing providers, medical
22 groups, individual practice associations, pharmacists, or other
23 entities that are associated with activities of the pharmacy benefits
24 manager to encourage formulary compliance or otherwise manage
25 prescription drug benefits.

26 4132. A pharmacy benefits manager shall disclose to a
27 prospective purchaser in writing all of the following:

28 (a) The aggregate amount, ~~and for a specified list of therapeutic~~
29 ~~classes, the specific amount,~~ of all rebates and other retrospective
30 utilization discounts that the pharmacy benefits manager estimates
31 it will receive, directly or indirectly, from pharmaceutical
32 manufacturers or labelers in connection with prescription drug
33 benefits related to the prospective purchaser. ~~A therapeutic class~~
34 ~~shall include at least two drugs.~~

35 (b) *For a specified list of therapeutic classes, the aggregate*
36 *amount for each therapeutic class of all rebates and other*
37 *retrospective utilization discounts that the pharmacy benefits*
38 *manager estimates it will receive, directly or indirectly, from*
39 *pharmaceutical manufacturers or labelers in connection with*

1 *prescription drug benefits specific to the prospective purchaser. A*
2 *therapeutic class shall include at least two drugs.*

3 (c) The nature, type, and amount of all other revenue that the
4 pharmacy benefits manager estimates it will receive, directly or
5 indirectly, from pharmaceutical manufacturers or labelers in
6 connection with prescription drug benefits related to the
7 prospective purchaser.

8 ~~(e)~~

9 (d) Any administrative or other fees charged by the pharmacy
10 benefits manager to the prospective purchaser.

11 ~~(d) The credentials of members of any pharmacy and~~
12 ~~therapeutic committee and any direct or indirect financial~~
13 ~~relationships between committee members and the~~
14 ~~pharmaceutical industry.~~

15 (e) Any arrangements with prescribing providers, medical
16 groups, individual practice associations, pharmacists, or other
17 entities that are associated with activities of the pharmacy benefits
18 manager to encourage formulary compliance or otherwise manage
19 prescription drug benefits.

20 4133. (a) A pharmacy benefits manager shall provide the
21 information described in Sections 4131 and 4132 within 30 days
22 of receipt of the request. If requested, the information shall be
23 provided no less than once each year.

24 (b) Except for utilization information, a pharmacy benefits
25 manager need not make the disclosures required in Sections 4131
26 and 4132 unless and until the purchaser or prospective purchaser
27 agrees in writing to maintain as confidential ~~any information that~~
28 ~~the pharmacy benefits manager reasonably considers proprietary~~
29 ~~any proprietary information.~~ That agreement may provide for
30 equitable and legal remedies in the event of a violation of the
31 agreement. That agreement may also include persons or entities
32 with whom the purchaser or prospective purchaser contracts to
33 provide consultation regarding pharmacy services. Proprietary
34 information includes trade secrets, and information on pricing,
35 costs, revenues, taxes, market share, negotiating strategies,
36 customers and personnel held by a pharmacy benefits manager and
37 used for its business purposes.

38 4134. A pharmacy benefits manager may not execute a
39 contract for the provision of pharmacy benefits management
40 services that fails to address the following items:

1 (a) The amount of the total revenues, rebates, and discounts
2 identified in ~~subdivisions (a) and (b) of Section 4131 and~~
3 ~~subdivisions (a) and (b)~~ *subdivisions (a), (b), and (c) of Section*
4 *4131 and subdivisions (a), (b), and (c) of Section 4132* that shall
5 be passed on to the purchaser.

6 (b) The disclosure or sale of enrollee utilization data by the
7 pharmacy benefits manager to any person or entity other than the
8 purchaser .

9 (c) Any administrative or other fees charged by the pharmacy
10 benefits manager to the purchaser .

11 (d) Conditions under which an audit will be conducted of the
12 contract for pharmacy benefits management services, who will
13 conduct the audit, and who will pay for the audit.

14 (e) Any revenues, rebates, or discounts received by the
15 pharmacy benefits manager directly or indirectly from entities
16 other than manufacturers and labelers.

17 (f) The process for development of formularies and
18 notification of changes to formularies, and approval of those
19 changes by the purchaser, provided that the pharmacy benefits
20 manager meets the requirements of Sections 4135 ~~and 4136~~, *4136,*
21 *and 4137.*

22 4135. (a) All members of a pharmacy and therapeutics
23 committee for a pharmacy benefits manager shall be physicians,
24 pharmacists, or other health care professionals, and a majority of
25 committee members shall ~~be actively practicing and not~~ *not be*
26 employed by the pharmacy benefits manager.

27 (b) *A pharmacy and therapeutics committee member shall not*
28 *be an officer, employee, director, or agent of, or any person who*
29 *has financial interest in, other than ownership of stock from open*
30 *market purchases of less than a nominal amount of the outstanding*
31 *stock of, pharmaceutical companies.*

32 4136. A pharmacy benefits manager shall report not less than
33 quarterly to the pharmacy and therapeutics committee which shall
34 monitor the health effects of medication substitutions on the health
35 of the patients, including identifying information from patients
36 and prescribers concerning the efficacy or health effects of
37 medication substitution.

38 4137. (a) A pharmacy benefits manager shall not substitute
39 a medication for another currently prescribed medication without

1 first obtaining express verifiable authorization from the prescriber
2 of the currently prescribed drug except in the following instances:

3 (1) As provided in Sections 4052.5 and 4073.

4 (2) If the medication substitution is initiated for patient safety
5 reasons.

6 (3) If the currently prescribed medication is no longer available
7 in the market.

8 (4) *If initiated pursuant to a drug utilization review.*

9 (5) *If required for coverage reasons where the prescribed drug
10 is not covered by the individual's formulary or plan.*

11 (b) The request for authorization to the prescriber shall include
12 all of the following:

13 (1) The cost savings for the purchaser, if any, that are a result
14 of the medication substitution.

15 (2) The difference, if any, in copayments or other out-of-pocket
16 costs paid by the patient in order to obtain the medication.

17 (3) The existence of any additional payments received by the
18 pharmacy benefits manager not reflected in the cost savings to the
19 purchaser.

20 (4) The circumstances, if any, under which the currently
21 prescribed medication will be covered.

22 (5) The circumstances and extent to which, if any, related
23 health care costs arising from the change in medications will be
24 compensated.

25 (6) Any known differences in potential effects on patient health
26 and safety, including side-effects.

27 (7) The name and title of the individual authorizing the change
28 if the authorization by the provider is given verbally.

29 (c) The pharmacy benefits manager shall not substitute a
30 medication for a currently prescribed medication unless the
31 pharmacy benefits manager communicates with the patient to
32 provide that patient or their representative the following
33 information:

34 (1) The proposed medication and the currently prescribed
35 medication.

36 (2) The difference in copayments or other out-of-pocket costs
37 paid by the patient, if any.

38 (3) Any known differences in potential effects on patient health
39 and safety, including side-effects, if any.

(4) The circumstances, if any, under which the currently prescribed medication will be covered.

(5) The cost savings for the purchaser, taking into account all discounts, rebates, or other payments that lower the cost of the medication to the purchaser.

(6) The existence of any additional payments received by the pharmacy benefits manager not reflected in the cost savings to the purchaser.

(7) A toll-free telephone number to communicate with the pharmacy benefits manager.

(8) The circumstances and the extent to which, if any, related health care costs will be compensated

~~(d) If either the prescriber or the patient instructs the pharmacy benefits manager to reverse or cease the substitution and if the currently prescribed medication remains on the formulary, the pharmacy benefits manager shall assure that the patient does not incur any additional copayments or other costs other than what the patient would have incurred without the substitution. The pharmacy benefits manager shall maintain a toll-free telephone number that is known to prescribers and patients.~~

(d) Unless a prescribed drug is no longer on the purchaser's formulary or the individual is unwilling to pay any higher applicable copayment or other costs, the pharmacy benefits manager shall cancel and reverse the medication substitution upon written or verbal instructions from a prescriber or the individual.

(1) The pharmacy benefits manager shall maintain a toll-free telephone number during normal business hours for a minimum of eight hours per day Monday through Friday for prescribers and patients.

(2) The pharmacy benefits manager shall not charge the individual any additional copayments or fees related to the replacement medication.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within

- 1 the meaning of Section 6 of Article XIII B of the California
- 2 Constitution.

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